Attorney Docket No: 6553-0501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATIONS

Applicant:	Jeppesen.	Examiner:	A. Bunin
Serial No:	10/629,511	Art Unit:	3743
Filed:	August 12, 2004		

Title: Method and Apparatus for Treating Obstructive Sleep Apnea Syndrome

DECLARATION OF RALPH D. CHABOT – RULE 1.132

I, Ralph D. Chabot, declare and state:

1. I am the Applicant's attorney for the pending U.S. application no. 10/629,511 entitled "Method and Apparatus for Treating Obstructive Sleep Apnea Syndrome".

2. As part of Examiner Bunin's Office Action dated 01-24-2006, the Katz et al. reference was cited for rejecting claims 32 and 36 under §103. Examiner Bunin cited this reference for the proposition that TENS is used to obtain a three-dimensional bite registration.

3. The cited Katz et al. reference, printed patent publication US2004/0115139, was published June 17, 2004 on utility application 10/685,986 filed October 15, 2003 that claimed priority to provisional application 60/418,789 filed October 15, 2002.

4. The filing date of the pending application, July 29, 2003, predates the filing of application no. 10/685,986.

5. I downloaded a copy of the Katz et al. provisional application 60/418,789 from the USPTO PAIR website and is attached to this declaration.

6. Provisional application 60/418,789 does not disclose Examiner Bunin's basis for rejection cited in ¶2 above, i.e. obtaining a three-dimensional bite registration in a neutral centric position via TENS.

7. Attorney Chabot respectfully submits that the Katz et al. reference is improper since Applicant's specification was filed prior to the filing date of the Katz et al reference which describes the use of TENS.

The Declarant is aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. All statements made of declarant's own knowledge are true and all statements made on information and belief are believed to be true.

I declare under the penalty of perjury that the foregoing is true and correct. Executed this 21st day of June, 2006, at Camarillo, California.

_____/rdc/_____
Ralph D. Chabot

10-17-00

PTO/SB/16 (10-01)
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISION[illegible] 37 CFR 1.53(c).

Express Mail Label No. EV172237199US

10/15/02 jc821 U.S. PTO

jc912 U.S. PTO 60/418789 10/15/02

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Howard	Katz	1450 Frazee Road #209 San Diego CA 92108

☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Controlled use of neurotoxins to prevent dental disease and assist treatment

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 6

☒ Drawing(s) *Number of Sheets* 2

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number

☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

☒ Payment by credit card. Form PTO-2038 is attached.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE [signature]

Date 101502

TYPED or PRINTED NAME Aaron Berk/US Corporations, Inc.

REGISTRATION NO. *(if appropriate)*

Docket Number:

TELEPHONE 76094308821

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

PROVISIONAL PATENT APPLICATION

TITLE: Controlled use of neurotoxins to prevent dental disease and assist treatment

INVENTORS: Howard Katz

TECHNICAL FIELD

This invention in the field of medical dentistry provides the administration to the patient of a therapeutically effective amount of a neurotoxin selected from a group consisting of Botulinum toxin types A, B, C, D, E, F and G to treat the following condition:

reduce and eliminate relative force imbalances in the mouths of mammals that are destructive, impede healing and interfere with treatment.

improve and accelerate re-attachment of all mammalian tissue after trauma, infection or treatment (counterbalancing the negative effects of Wolf's Law.)

accelerate tooth movement in all mammals during orthodontic treatment by allowing the dominant vector of force to be derived from the orthodontic appliances

prolong the life of all dental materials and natural tooth in all mammals by limiting the excessive and destructive natural biting forces in individuals that have compromised tooth strength relative to the force of their bite.

BACKGROUND ART

Many individuals experience excessive functional forces in their mouths relative to the **strength of their teeth**. Oral tissue and dental restorative materials may be able to withstand natural forces in certain individuals but not in everybody. The damage caused by excessive biting forces and dental trauma on these oral tissues and dental materials are still being treated with intra- oral appliances, sophisticated dental restorations, medications and/or surgery. Successful treatment is limited because the main cause of the problem, the excessive biting forces have not been harnessed.
Compliance with protective removable appliances worn over the teeth is very low. The continued use of analgesics and anti-inflammatories for associated tooth, muscle and joint pain are neither ideal nor conducive to health. Sophisticated restorations are very expensive, involve the removal of additional healthy tooth material and the most esthetic, conservative restorations may not withstand the forces applied to them. The dental profession has always prided itself in that the focus of oral healthcare has been based on

prevention. Restoring damage to the tissues in the mouth is not the ideal especially if this damage could have been prevented.
The most effective way to prevent damage to dental hard tissue and restorations is to de-program the muscles responsible for the relatively excessive functional force.

Neurotoxins have been used for denervating muscles and in other treatments for facial dystonia and facial wrinkles. A toxin capable of blocking neuromuscular activity is administered to masticatory muscle responsible for the unnecessary excessive force. Resulting limited paralysis of the muscles alleviates the detrimental forces and allows unimpeded therapy and healing on all tissues including teeth, gums, bone (see Wolff's Law), ligaments, tendons and muscles. The preferred toxin for use is *a neurotoxin. The neurotoxin* improves and accelerates re-attachment of all mammalian tissue after trauma, infection or treatment

"In the 19th century, surgeon Julius Wolff proposed that mechanical stress was responsible for determining the architecture of bone...."

"Remodeling of bone ... occurs in response to physical stresses - or to the lack of them - in that bone is deposited in sites subjected to stress and is resorbed from sites where there is little stress". The inherent architecture of bone is influenced by the mechanical stresses associated with normal function.

Mechanical stress is responsible for determining the architecture of all tissues during function and healing including bone, muscle, ligaments, tendons.
Neurotoxin will limit the undesired forces during healing.

Neurotoxin prolongs the life of all dental restorations and weakened teeth in all mammals by limiting the overloaded natural biting forces in individuals that have compromised tooth strength relative to the force of their bite.

Neurotoxin, produced by the bacterium Clostridium botulinum reversibly paralyzes striated muscle when administered in sub-lethal doses. Neurotoxin has been used in the treatment in a number of neuromuscular disorders and conditions involving muscular spasm including various forms of dystonia, hemifacial spasm, tremor, spasticity, anal fissures and various ophthalmologic conditions (c.f. A. Carruthers et al (1996), Botulinum A Exotoxin Use in Clinical Dermatology; Journal of the American Academy of Dermatology 34: 788-797).

Neurotoxin is a generic term covering a family of toxins produced by C. botulinum comprising up to eight serologically distinct forms (A, B, C.sub.1, C.sub.2, D, E, F and G). These toxins, which are among the most powerful neuroparalytic agents known (c.f. Melling, J. et al (1988) Clostridium Botulinum: Nature and Preparation for Clinical Use; Eye 2: 16-23). Serotypes A, B and F are the most potent.

BTX-A serotype is available commercially under the trademarks BOTOX.TM. (Allergan, Inc., Irvine, Calif., U.S.A.) and DYSPORT.TM. (Speywood Pharmaceuticals, Ltd., Maidenhead, U. K.). The initial cosmetic use of BTX was for treatment of forehead frown

lines as reported in J. Carruthers and A. Carruthers (1992) "Treatment of Glabellar Frown Lines with C. Botulinum-A Exotoxin"; J. Dermatol. Surge Oncol. 18: 17-21. Subsequently, various facial treatments employing BTX have been reported but use of BTX for treatment of midfacial defects has been limited.

Application of BTX near the mouth has been limited to treatment of neuromuscular disorder. For example, hemifacial spasm has been treated by BTX injection to the zygomaticus muscle but the modeolus adjacent the corner of the mouth is avoided (J. Carruthers and A. Carruthers (1996) Botulinum A Exotoxin in Clinical Ophthalmology; Can. J. Ophthalmol. 31: 389-400).

Facial synkinesis and asymmetry caused by facial nerve palsy (Armstrong, M .W. J. et al. (1996) are treated with BTX."Treatment of Facial Synkinesis and Facial Asymmetry with ***Botulinum Toxin*** Type A Following Nerve Palsy", Clin. Otolaryngol. 21:15-20). In the latter procedure, the levator anguli oris, zygomaticus major, rizorius and depressor anguli oris muscles associated with the mouth together with various muscles associated with the eye on the normal side of a patient's face were all treated as a group in order to affect the entire vertical symmetry of a patient's face to compensate for effects of nerve palsy on the untreated side of the face.

While BTX treatment of the platysma muscle has been performed for treatment of neck lines and banding, it has also been noted that injection of BTX into the platysma produces an uplift of the mouth (F. S. Brandt and B. Bellman (1998) Cosmetic Use of Botulinum A Exotoxin for the Aging Neck; Dermatol. Surg. 24: 1232-1234). Injection of BTX into the point of the chin has also been done for treatment of prominent mental crease (A. Carruthers and J. Carruthers; "Cosmetic Uses of Botulinum A Exotoxin"; In: James, W. D. et al Eds. Advances in Dermatology (1997) Mosby-Yearbook, Chicago.

METHOD

The method comprises of administering by intramuscular injection an effective amount of a botulinum toxin to a muscle of the face or mouth of a patient, thereby relieving the specified conditions within one to seven days, wherein the condition is associated with a muscle contraction. The botulinum toxin is administered in an amount of between 0.01 units and 500 units.The dose is effective from three to four months and can be repeated as often as necessary. Often the de- programming of the muscle eliminates the necessity for repeated doses.

Simultaneous bilateral BTX injections to facial muscles can be administered without embarrassment to the appearance and function of the mouth. The direction of muscle fibers and contraction forces are re-aligned and the function of the patient's chewing is not impeded.

BENEFITS

The inventors have now found that quantitating these excessive forces then reducing the forces in a controlled and measured fashion with neurotoxins will treat the following conditions.

1.Headaches caused by Chronic Clenching Syndrome is when the patient bites and stays in a fixed position by contraction of the muscles, particularly the tempuralis. The muscles eventually go into spasm causing pain.

2.dental sensitivity – trauma to the periodontal ligament caused by clenching results in inflammation of the PDL and dental pulp manifested as temperature sensitivity.

3.neck strain – the head tilts backwards to compensate for constant clenching on the front teeth, and, tilts forward to compensate for clenching on the back teeth. Both cause fatigue and cramping in the neck muscles.

4. ringing ears (tinnitus) – tensor tympani and tensor levi palatini within the ear tense with constant clenching of the jaw muscles causing ringing

(Periodontics)

5.limiting biting force after periodontal surgery especially where there is limited crown to bone length. Excessive forces may jeopardize dental stability and contribute to additional tooth loosening.

6.Gum recession caused by lingual or facial direction of force. Gum and bone are lost in front of the direction of force especially in when the force is directed towards the lip or cheek side of the tooth.
Torquing the gum and bone away from the periodontal ligament attachments causes gingival recession and bone loss, followed by sensitivity and decay on these teeth. The force traumatizing the teeth also contribute to sensitivity.

7.Bone loss associated with either advanced periodontitis or osteoporosis provides less support for the teeth. Regular biting forces in this compromised position will lever the remaining bone away from the roots causing accelerated bone loss, loosening and loss of teeth.

(Oral Surgery)

8.limiting muscle contraction after trauma to muscles, tendons, ligaments or bone reduces tensile strain on the damaged tissue allowing healing in reduced time with less pain and minimal internal or external fixation during repair and rehabilitation

9.when multiple implants or immediate loaded implants are placed - to prevent overloading the implants before osseo-integration. Overloading the implants results in implant failure either by fracture or loosening of the implant components or prevention of osseo-integration.

10.re- implanting teeth that have been traumatically avulsed. The loosened teeth will lose their vitality and not re-attach to alveolar bone when loaded with relatively excessive functional force

(Operative General Dentistry)

11.Abfraction - Teeth have the ability to flex, usually at the enamel-dentine junction. The crystalline enamel of the flexing tooth fractures at the point of maximum flexation next to the gum while grinding. The resultant loss of enamel and groove on the sides of the teeth makes them sensitive and more susceptible to decay.

12.protecting all temporary and all permanent dental restorative materials from destructive forces:
acrylics, resins, composites, glass ionomers, amalgams, ceramics, porcelains, vitallium, chrome cobalt, fiber re-enforced posts, titanium and stainless steel posts, zirconia

13.continued fracture of dentures, clasps and attachments especially when the denture opposes natural teeth

14. protecting natural and artificial tooth material, including cusps, clasps, attachments, posts and roots from fracturing with excessively forceful chewing function.

15. maintaining vertical dimension during prolonged temporization. Teeth are covered with temporary crowns before being crowned. These temporaries that are used to open the bite are often are left for prolonged period of times up to a few years. In a mouth where the occlusion has been destroyed by very aggressive chewing function these temporaries often do not last, or are prematurely worn down before the therapeutic effects of bite opening can be assessed.
Temporary crowns are also left for prolonged periods when the dentist is waiting for periodontal healing, assessing how much to open the bite or when the patient cannot afford permanent crowns.

(Orthodontics)

16.shorten orthodontic treatment time by reducing the load on teeth especially with a very powerful vertical component of force on tooth and bone.

17.limit bone loss during orthodontics caused by traumatizing teeth that interfere with a comfortable bite while they are being moved and are out of occlusion

18.development of deep overbite. The excessive vertical pull on the jaws by the jaw closing muscles plays a major part in development of a deep overbite especially during facial development

19.anterior, lateral or bilateral tongue thrust caused by swallowing with the tongue positioned between the teeth forming the oral seal while swallowing (instead of behind the upper front teeth). Neurotoxin in the genioglossus will assist in prevention

SUMMARY OF THE INVENTION

This invention provides the use of ***a neurotoxin*** to cause limited paralysis of the muscles of mastication in a patient

This invention provides a method for preventing damage and augmenting treatment to the teeth, gums, periodontal ligaments, alveolar bone, dental restorative materials, the tempero mandibular joint comprising:

a) locating the muscles of mastication of the said mouth

b) measuring the bite forces with a bite pressure sensor (Tekscan, gnathomamometer, strain gauges) or measuring the indentations made by the teeth cusps when the said subject bites with maximum force into a piece of balsam wood of fixed dimensions.

c) Injecting into the muscles responsible for the deleterious function a quantity of ***Botulinum toxin*** (BTX) sufficient to cause reduction in contraction force.

d) This will reduce the forces applied to all natural tissue and restorative materials in the mouth. These can be re-measured and the decrease quantitated after the BTX has had its desired effects

In this invention, BTX is simultaneously injected into symmetric muscles on opposite sides of the face. By simultaneously, it is meant that the injection into symmetric muscles occurs as part of the same treatment, although one side of the mouth may be selected for injection before the other during a treatment session.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1: is a frontal view showing musculature of the human face and neck.

FIG. 2: is a frontal view of a human face and neck showing the general location of the muscles and sites for BTX injection according to this invention.

Yahooligans! Reference: Gray's Anatomy

Search Gray's Anatomy

Enter a word or phrase to look up (e.g., **norma lateralis**):

Search

<< PREVIOUS

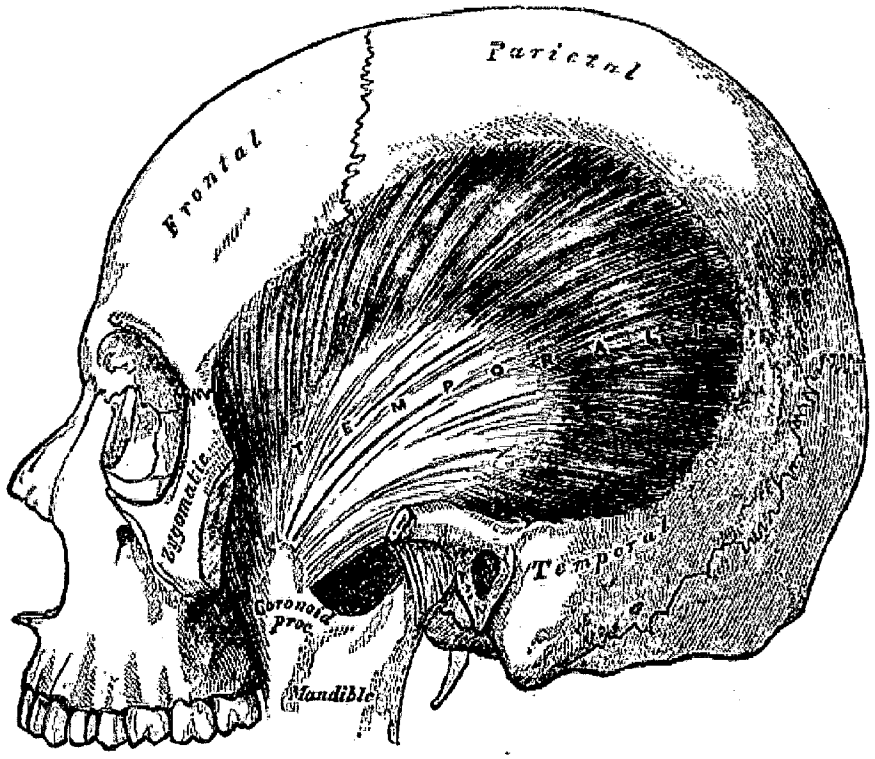
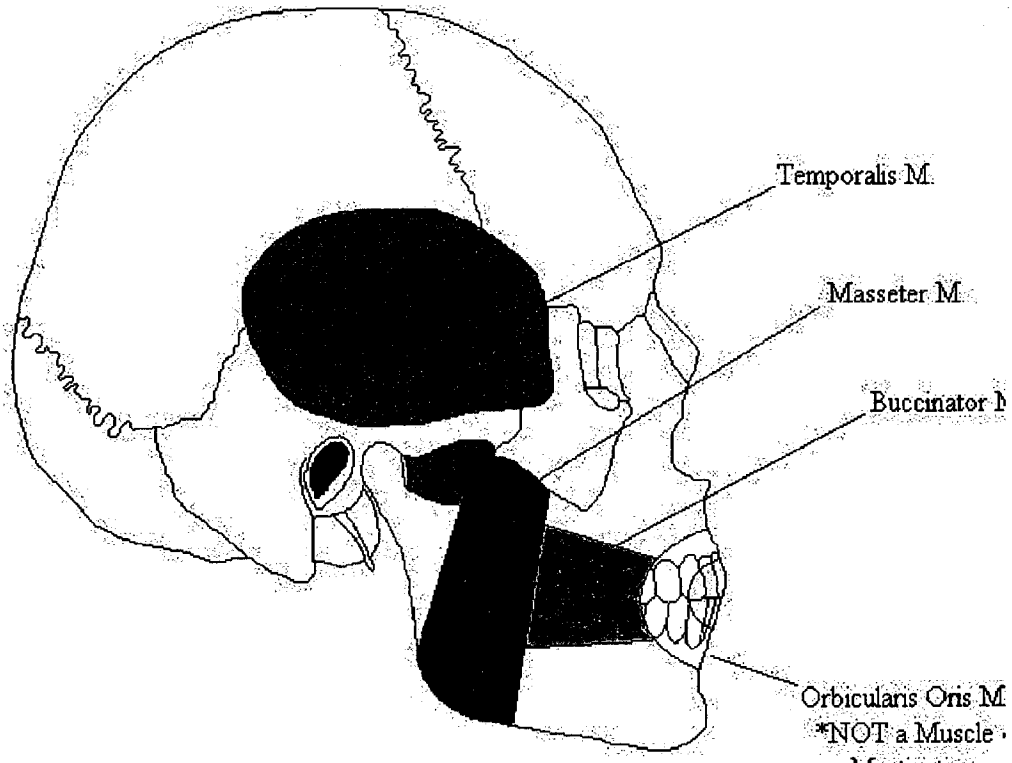


FIG. 382– The Temporalis; the zygomatic arch and Masseter have been removed.

(See associated text)

<< PREVIOUS



Muscles of Mastication I: Lateral View